

## **REMARKS**

Reconsideration and withdrawal of the rejections of the claimed invention is respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 1-18 are pending in this application. In order to expedite prosecution, the applicants have amended claim 1 to recite the transitional claim term of ---consists of---. The applicants reserve the right to pursue the scope of the originally filed claims in a continuing application. Claim 9 has been amended to add the limitation of previous claim 10; pending claim 10 has been amended to incorporate the data represented by Examples 1-11 as depicted in Table 7. New claims 11-18 have been added which provide further embodiments of claim 1. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

### **II. THE 35 U.S.C. 112, 2<sup>nd</sup> PARAGRAPH REJECTION HAS BEEN OVERCOME**

Claim 1 is rejected as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. The applicants request reconsideration of this rejection in light of the amendments made to claim 1 above.

### **III. THE 35 U.S.C. 102(a) REJECTION HAS BEEN OVERCOME**

A. Claims 8-10 were rejected as allegedly being anticipated by Dobrozi et al. (U.S. Patent 6,503,955 - "Dobrozi"). The applicants request reconsideration of this rejection for the following reasons. (Note: The limitation to claim 10 as currently amended was not before the Examiner in the previous Office Action)

The standard to establish anticipation of the applicants' claims by a prior art reference, requires that all elements of the applicants claimed invention must be described in the prior art reference and be presented in as complete detail as is contained in the claim. *See MPEP 2131, see also In re Spada*, 15 USPQ2d 1655, (Fed. Cir. 1990) ("Rejection for anticipation requires, as

first step in inquiry, that all elements of claimed invention be described in single reference, and such reference must describe applicant's claimed invention sufficiently to have placed person of ordinary skill in possession of it."). However, Dobrozsi does not meet this standard for anticipation.

The applicants' solution of claim 8 requires a combination of: (1) a non-ionic surfactant, (2) a non-osmotic pressure regulating agent and (3) is free of an ionic compound. Moreover, the solution must be suitable for storing the drug delivery ophthalmic lens of claim 6.

However, there is no indication that Dobrozsi ever teaches all of the required elements are present in combination. The specification up to the Examples in Dobrozsi reads like a wish-list and fails to meet the "complete detail" requirement to establish anticipation.

The Examples in Dobrozsi are defective for establishing anticipation for various reasons. Some of the examples fail the "free of an ionic compound" requirement (see Examples I-III, VII, VIII, X-XIV, XVIII (Composition for the Treatment of Ulcers)<sup>1</sup>, XIX and XX). Examples V, VI, XVI and XVII lack element (2) and Examples IV, IX and XV are not suitable solutions for storing the drug delivery ophthalmic lens of claim 6 as each example contains over 40 w/w% of both (1) and (2).

**B. Claims 1, 3, 4 and 5 were rejected as allegedly being anticipated by Wichterle et al. (U.S. Patent 3,220,960 - "Wichterle").** The applicants request reconsideration of this rejection for the following reasons.

Wichterle does not anticipate the applicants' claimed invention because Wichterle does not teach every element of the applicants' claims, i.e. there is no teaching for at least one phosphate group-containing methacrylate represented by formula (I) in applicants claim 1 or any indication that the polymer *consists of* (a), (b), (c) and (d) as described in amended claim 1.

**VII. THE 35 U.S.C. 103(a) REJECTION HAS BEEN OVERCOME**

**A. Claims 6 and 7 were rejected as allegedly being obvious by Sulc et al. (U.S. Patent 5,270,415 - "Sulc") in view of Aiache et al. (U.S. Patent 6,713,080 - "Aiache").** The applicants request reconsideration of this rejection for the following reasons. (Note: New claims 11 and 12 was not before the Examiner in the previous Office Action)

The standard for establishing obviousness requires that all claim limitations must be taught or suggested by the prior art or from within the knowledge available to those of ordinary skill in the art. However, the combination of Sulc in view of Aiche does not meet this standard.

First, the applicants note that the passage and claim referred to in the Office Action does not support the statement "Sulc et al. teach a contact lens as a drug delivery system...". More accurately, Sulc would describe either a contact lens OR a drug delivery system. Col. 5, lines 3-6 reads as follows: "*In addition* to contact lenses, the balanced charge polymer of this invention *can be used* to prepare implantable prostheses, e.g. intra-corneal implants, intra-ocular lenses, etc., drug delivery systems, and the like."

Second, the Office Action recited a 92% mol% from Example 17 which was evidently judged to be close enough to the applicants' upper range of 90% to be obvious. However, this holding is erroneous on two counts: (1) there was no reason for one of ordinary skill in the art to optimize the mol.% ratio; and (2) the upper range of 90% was a critical range which was unknown by those of skill in the art.

As noted in MPEP 2144.05 section II (Optimization of Ranges) "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)." Nothing in Sulc makes the suggestion that the mol.% ratio of anionic to cationic components is a results effective variable.

In addition, it was explained in the specification that increasing the anionic monomer to greater than 90% causes the charge of the cationic group acting as a drug ligand in the polymer gel gets cancelled, so the cationic group does not generate ionic interaction with the drug having an anionic group, thus failing to include the drug in the polymer gel.<sup>2</sup> As such, the teaching from Example 17 of Sulc does not result in a lens which is capable of being drug delivery system.

Aiache is only relied upon for a generic teaching of drug delivery from an ophthalmic lens and does not remedy the deficiencies of the Sulc reference.

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<sup>1</sup> Note that the patent refers to this as "Example XIII", however, this is believed to be a typographical error as Example XIII was already described and "Example XIII" follows Example XVII (Composition for the Treatment of Glaucoma).

<sup>2</sup> See paragraph [0032] from the publication of this application (U.S. Patent Application Publication 2006-0187410)

Therefore, the limitation of an “anionic monomer in a ratio of 30 to 90 mol % to the cationic monomer” is not a trivial limitation which is obvious from the combination of Sulc and Aiache.

**B. Claims 1 and 2 were rejected as allegedly being obvious by Nakamae et al. (Makromolekulare Chemie-Macromolecular Chemistry and Physics 1992 193:983-990 - “Nakamae”) in view of Janda et al. (U.S. Patent 4,640,936 - “Janda”) and Aiache et al.** The applicants request reconsideration of this rejection for the following reasons. (Note: New claims 13-18 was not before the Examiner in the previous Office Action)

Considerations of obviousness require that both the applicants’ invention and the cited references be considered as a whole. *See MPEP 2141*. The applicants’ claimed invention is directed toward a **drug delivery ophthalmic lens**, which consists of the components (a) – (d) described above in claim 1. However, none of the references cited in the rejection are directed toward a lens.

Nakamae is directed toward a hydrogel subject to swelling and deswelling, not an ophthalmic lens (see Abstract). As such, one of ordinary skill in the art would not find a hydrogel subject to swelling or deswelling as being equivalent to an ophthalmic lens. Therefore, despite using a phosphate containing monomer and a hydrophilic monomer as part of their hydrogel, Nakamae does not produce the ophthalmic lens of the applicants’ invention and the combination with Jana and Aiache does not remedy the deficiencies of Nakamae.

Jana is directed toward a photopolymerizable phosphate-containing adhesion promoting dental composition, i.e. a dental glue which promotes adhesion of resin-based dental restorative materials to the tooth. Other than having a phosphate containing monomer as part of their polymer, Jana is unrelated to both Nakamae and the applicants’ invention, i.e. one of ordinary skill in the art would not have a reasonable expectation of success that combining a hydrogel with a dental glue would yield an ophthalmic lens.

In addition, even if Nakamae and Jana could be combined, there is still no recitation of the other elements of the applicants’ claimed invention, i.e. (c) and (d), in combination with elements (a) and (b).

Aiache is only relied upon for a generic teaching of drug delivery from an ophthalmic lens and does not remedy the deficiencies of the Nakamae and Jana and reference.

Therefore, the applicants' claimed invention is not rendered obvious by the combination of Nakamae, Jana and Aiache.

**CONCLUSION**

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution. The Commission is authorized to charge any fee occasioned by this paper, or credit any overpayment of such fees, to Deposit Account No. 50-0320.

Respectfully submitted,  
FROMMER LAWRENCE & HAUG LLP

By: /Howard C. Lee/  
Marilyn M. Brogan      Howard C. Lee  
Reg. No. 31,223      Reg. No. 48,104  
Telephone:      (212) 588-0800  
Facsimile:      (212) 588-0500